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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/023,831	Applicant(s) VAUGHAN ET AL.	
	Examiner Daniel M Sullivan	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a reply to the Paper filed 28 June 2004 in response to the Non-Final Office Action mailed 26 January 2004. Claims 31-35 were considered in the 26 January Office Action. Claims 31, 32 and 34 were amended in the 28 June Paper. Claims 31-35 are presently pending and under consideration.

Response to Amendments and Arguments

Sequence Compliance

In the previous Office Action, Applicant was requested to submit a statement in compliance with Rule 1.825(a), which requires that any amendment to a paper copy of the 'Sequence Listing' must include a statement that the substitute sheets include no new matter. In response, Applicant has submitted a copy of the statement in accordance with Rule 1.821 that was originally filed with the substitute sequence listing on 19 June 2002. However, the Examiner can find no statement that the submission contains no new matter. Therefore, the submission is still defective for the reasons stated in the 26 January Office Action.

Claim Rejections - 35 USC § 101

Rejection of claims 31-35 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn.

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Claim Rejections - 35 USC § 112

First paragraph

Rejection of claim 34 under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claim is withdrawn in view of the amendments thereto.

Claims 31-33 and 35 stand rejected under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claimed subject matter for reasons of record. It was indicated in the previous Office Action that the specification, while being enabling for a hydroxylated triple helical protein wherein the protein is a collagen, does not reasonably provide enablement for the broad scope of polypeptides encompassed by the claims. The rejection was made on the grounds that, although the art teaches that collagens are therapeutically useful, neither the art nor the instant specification teaches how any protein having the structure of a hydroxylated triple helical protein can be applied therapeutically. The skilled artisan armed with no more than the teachings available at the time of filing would not know how to use the vast majority of therapeutic products encompassed by the claims, and would not be able to distinguish which hydroxylated triple helical proteins could be substituted for collagen in therapeutic applications without having to resort to blind trial and error experimentation to make and test each of the proteins encompassed by the claims. Given the tremendous scope of the claims this would clearly require undue experimentation. Therefore, practicing the claimed invention commensurate with its full scope would require undue experimentation.

In response, Applicant merely asserts that the specification provides the skilled artisan with sufficient information to reproduce the claimed invention without inventive activity. This

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argument has been fully considered but is not deemed persuasive because it does not address the underlying reasons for rejection set forth. A *prima facie* case was made in the previous Office Action based on the factual inquiries set forth in *In re Wands*, (CA FC) 8 USPQ2d 1400. In response Applicant merely dismisses the rejection without pointing out any flaws in the case set forth in the Office Action. This is not persuasive. Therefore the claims stand rejected under 35 U.S.C. §112, first paragraph, for reasons of record.

Second paragraph

Rejection of claims 31-35 under 35 U.S.C. 112, second paragraph, as indefinite is withdrawn.

Claim Rejections - 35 USC § 102

Claims 31-33 stand rejected under 35 U.S.C. 102(b) as being anticipated by Fields *et al.* (1996) *Lett. Peptide Sci.* 3:3-16.

In response to the *prima facie* case of record, Applicant has amended claim 31 such that the claimed protein must comprise at least one polypeptide or peptide domain which is heterologous to collagen proteins and which does not comprise a triple helical forming repeating sequence. Applicant argues that Fields *et al.* does not contemplate such a peptide or polypeptide. However, in Figure 1, Fields *et al.* describes a triple helical protein according to the claimed invention which also comprises the peptide sequence "lys-lys-tyr-gly", which meets the limitation of a peptide domain which is heterologous to collagen proteins and which does not

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comprise a triple helical forming repeating sequence. Therefore, the hydroxylated triple helical protein of Fields *et al.* anticipates the instant claimed invention, and the claims stand rejected.

Rejection of claims 31, 32 and 34 under 35 U.S.C. 102(b) as being anticipated by Silver *et al.* (1992) U.S. Patent No. 5,171,273 is withdrawn in view of the amendments to the claims.

Claims 31 and 32 stand rejected under 35 U.S.C. 102(b) as being anticipated by any one of Swiss-Prot database entries P02745 (1986), P07714 (1988), P35247 (1994), P11226 (1989), P23805 (1991), or P21757 (1991).

In response to the *prima facie* case of record, Applicant alleges, "the cited database entries are silent with regard to a hydroxylated triple helical peptide that contains as [sic] least one heterologous domain as defined in amended claim 31." However, Applicant is reminded that the polypeptide or peptide domain of claim 31 is limited to being "heterologous to collagen" and not heterologous to the protein comprising the triple helical domain. In addition to the collagen-repeat domain, P02745 comprises sequence unique to a complement protein, P35247 and P07714 comprise sequence unique to pulmonary surfactant proteins, P21757 comprises sequence unique to macrophage scavenger receptor proteins, P23805 comprises sequence unique to conglutinin proteins and P11226 comprises sequence unique to mannose binding protein proteins, each of which are heterologous to collagen. Thus, each of the cited database entries comprise all of the limitations of the instant claims 31 and 32. Therefore, the claims stand rejected under 35 U.S.C. §102 as anticipated by the art.

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Claims 31-35 stand rejected under 35 U.S.C. 102(e) as being anticipated by St. Pierre *et al.* U.S. Patent No. 5,856,308 (filed 27 September 1996).

In response to the *prima facie* case of record, Applicant again alleges that the cited art does not teach a triple helical peptide that contains at least one heterologous domain. However, in Formula A (column 3), St Pierre *et al.* describes a hydroxylated triple helical protein according to the limitations of claim 31 and wherein the protein comprises a "polymer". In column 5, line 60, St. Pierre *et al.* teaches that this polymer can be a peptide selected from polyglutamic acid, polyaspartic acid and polylysine, which meets the limitation of at least one peptide domain which is heterologous to collagen proteins and which does not comprise a triple helical forming repeating sequence. Therefore, the products described by St. Pierre *et al.* comprise all of the limitations of the presently claimed invention and anticipate the claims as amended.

New Grounds Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

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The MPEP states, “[i]f new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. §112, first paragraph-written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).” (MPEP § 2163.06). The MPEP further states, “[w]henever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in the application” (*Id.*, § 2163.02). The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

In the instant case, claim 31 has been amended such that n in the sequence $(\text{GlyXY})_n$ is limited to being 2 to 1500. However, the only recitation of 2 to 1500 GlyXY repeats is in reference to the $(\text{GlyXY})_i$ comprised within domain Z. In contrast the term $(\text{GlyXY})_n$ is optionally comprised within the A and the Examiner can find no statement in the specification that would lead the skilled artisan to believe that the limitations of $(\text{GlyXY})_i$ are the same as those of $(\text{GlyXY})_n$. Thus, there does not appear to be any support, either explicitly or implicitly, for the limitation “ n is 2 to 1500”. Instead, the specification does not appear to contemplate any limitation on the size of the GlyXY repeat that could be comprised within the A or D terms. This could be expressed by stating that n is 0 to ∞ .

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Claim 31 has also been amended such that the description of terms B and C includes the proviso "at least one of m and o is 1". The examiner can find no explicit support for this proviso in the originally filed specification and can find no statement that would clearly convey to one of ordinary skill a subgenus which excludes embodiments wherein both m and o are zero. In fact, the original disclosure explicitly states that the values for m and o are "selected independently". In contrast, in the amended claim, the value assigned to m is dependent upon the value of m (*i.e.*, if o is 0 m cannot be 0) and *vice versa*. Thus, the limitation of the claimed subject matter to exclude a subset of embodiments wherein both m and o are zero is neither explicitly nor implicitly supported by the originally filed disclosure. Therefore, claims 31-35 are rejected under 35 U.S.C. §112, first paragraph, as lacking descriptive support in the original disclosure.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779.

The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M Sullivan, Ph.D.
Examiner
Art Unit 1636


PRIMARY EXAMINER